



1634
PATENTS
\$

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stuyver, Lieven *et al.*

Serial No. 10/008,140

Filed: October 18, 2001

For: Simultaneous Quantification of Nucleic Acids in Diseased Cells

Commissioner for Patents
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

The citation of information on the attached Form PTO-1449, "List of Art Cited by Applicant" is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each cited item is enclosed as well as a copy of the PCT Search Report.

The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

Applicants enclose a check in the amount of \$180.00 for submission of an Information Disclosure Statement. Although no additional fees are believed by the Applicants to be due, the Commissioner is hereby authorized to charge any requisite fees or credit any overpayment to Deposit Account No. 11-0980.

05/27/2003 MMCHAMM1 00000006 10008140

01 FC:1806

180.00 OP

Respectfully submitted,

Stephanie D. Adams, Ph.D.
Reg. No. 47, 378

King & Spalding
45th Floor, 191 Peachtree Street, N.E.
Atlanta, GA 30303
404.572.3404
Fax: 404-572-5145



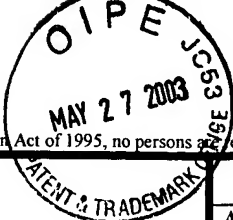
CERTIFICATE OF MAILING

I hereby certify that this Supplemental Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.


Susanne Hollinger, Ph.D.

May 19, 2003

Please type a plus sign (+) inside this box → ☐



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Submitted for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Complete if Known	
				Application Number	10/008,140
				Filing Date	October 18, 2001
				First Named Inventor	Stuyver, Lieven J. <i>et al.</i>
				Group Art Unit	1634
Sheet	1	of	2	Attorney Docket Number	PHA 1040 08841.105035

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pgs, Clmns, Lns, Where Relevant Passages/Relevant Figs Appear
		Number	Kind Code (if known)			
	AA	6,218,117		Herrnstadt et al	04-17-2001	
	AB	6,489,095		Herrnstadt et al	12-03-2002	
	AC	2002/0164612		van Gemen et al	11-07-2002	

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document DD-MM-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number	Kind Code ² (if known)				
	AD	EP	01202168.9		PrimaGen B.V.			
	AE	EP	1211323		Amsterdam Support Diagnostics B.V.	05-06-2002		
	AF	EP	1229130		PrimaGen B.V.	07-08-2002		
	AG	WO	97/39149		Ramot University	23-10-1997		
	AH	WO	99/51776		Southern Res Inst	14-10-1999		
	AI	WO	99/66075		Mitokor	23-12-1999		
	AJ	WO	00/44935		Klein Dieter	03-08-00		
	AK	WO	02/097124		The Univ of British Columbia	05-12-2002		
	AL	WO	02/46470		PrimaGen B.V.	13-06-2002		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐

MAY 27 2003

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

Submitted for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/008,140
				Filing Date	October 18, 2001
				First Named Inventor	Stuyver, Lieven J. <i>et al.</i>
				Group Art Unit	1634
				Attorney Docket Number	PHA 1040 08841.105035
Sheet	2	of	2		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	BA	BOULTWOOD, J. <i>et al.</i> , <i>British Journal of Hematology</i> , vol. 95, 1996., pp. 426-431	
	BB	DESJARDIN, L. E. <i>et al.</i> , <i>American Journal of Respiratory and Critical Care Medicine</i> , vol. 160, no. 1, July 1999., pp. 203-210	
	BC	ISHIDA, K. <i>et al.</i> , <i>Forensic Science International</i> , vol. 113, no. 1-3, 11 September 2000, pp. 127-131.	
	BD	JOSEFSSON A. M. <i>et al.</i> , <i>Lancet</i> , vol. 335, no. 9222, June 24, 2000, pp. 2189-2193.	
	BE	MESINK E. <i>et al.</i> , <i>British Journal of Haematology</i> , vol. 102, no. 3, August 1998, pp. 768-774.	
	BF	OVERBERGH, L. <i>et al.</i> , <i>Cytokine</i> , vol. 11, no. 4, April 1999, pp. 305-312.	
	BG	TEPPER <i>et al.</i> , <i>Journal of Cellular Biochemistry</i> , vol 52, 1993, pp. 352-361	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
2. This communication is not the international search report which will be established according to Article 18 and Rule 43. see 'Invitation to pay additional fees'
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 99 51776 A (SOUTHERN RES INST) 14 October 1999 (1999-10-14) page 4, line 9 -page 5, line 3 page 5, line 25 -page 6, line 11 page 8, line 10 - line 16 page 8, line 30 -page 10, line 21 page 12, line 16 - line 32 claims 1-10 ---	1-12
Y	OVERBERGH LUT ET AL: "Quantification of murine cytokine mRNAs using real time quantitative Reverse Transcriptase PCR." CYTOKINE, vol. 11, no. 4, April 1999 (1999-04), pages 305-312, XP002227388 ISSN: 1043-4666 the whole document especially page 307 right-hand column second paragraph and page 312 left-hand column second paragraph --- -/--	1-12

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	ISHIDA KAORI ET AL: "Novel approach to quantitative reverse transcription PCR assay of mRNA component in autopsy material using the TaqMan fluorogenic detection system: Dynamics of pulmonary surfactant apoprotein A." FORENSIC SCIENCE INTERNATIONAL, vol. 113, no. 1-3, 11 September 2000 (2000-09-11), pages 127-131, XP002227389 ISSN: 0379-0738 the whole document especially page 128 right-hand column lines 13-page 129 left hand-column line 23	1-12
Y	MENSINK E ET AL: "Quantitation of minimal residual disease in Philadelphia chromosome positive chronic myeloid leukaemia patients using real-time quantitative RT-PCR." BRITISH JOURNAL OF HAEMATOLOGY, vol. 102, no. 3, August 1998 (1998-08), pages 768-774, XP002227390 ISSN: 0007-1048 the whole document	1-12
A	JOSEFSSON A M ET AL: "Viral load of human papilloma virus 16 as a determinant for development of cervical carcinoma in situ: a nested case-control study" LANCET, vol. 355, no. 9222, 24 June 2000 (2000-06-24), pages 2189-2193, XP004263606 ISSN: 0140-6736 the whole document	1-12
A	DESJARDIN LUCY E ET AL: "Measurement of sputum Mycobacterium tuberculosis messenger RNA as a surrogate for response to chemotherapy." AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE, vol. 160, no. 1, July 1999 (1999-07), pages 203-210, XP002227391 ISSN: 1073-449X page 204, left-hand column, paragraph 3 - paragraph 4 page 205, left-hand column, paragraph 6 - paragraph 7 figures 1,2 page 207. left-hand column. paragraph 2 discussion	1-12

-/--

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 44935 A (KLEIN DIETER ;GUENZBURG WALTER (AT); SALMONS BRIAN (DE); BAVARIAN) 3 August 2000 (2000-08-03) page 4, line 23 -page 6, line 7 page 7, line 6 - line 21 page 8, line 1 -page 9, line 15 -----	1-12

Patent Family Annex
Information on patent family members

National Application No
PCT/US 01/47223

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 9951776	A	14-10-1999	AU	3474499 A	25-10-1999
			WO	9951776 A1	14-10-1999
<hr/>					
WO 0044935	A	03-08-2000	AU	2799400 A	18-08-2000
			WO	0044935 A2	03-08-2000
			EP	1147225 A1	24-10-2001
<hr/>					

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Claims Nos.: 10,11 (both partially)

Notwithstanding the lack of NON-UNITY there exist as well lack of clarity in the first invention:

Present claims 10 and 11 relate to a nucleic acid sequence from beta-actin and GAPDH defined as viral nucleic acid (see also claim 6). The use of this definition in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT since both beta-actin and GAPDH are housekeeping (constitutive) genes which do not exist in viruses. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search has been restricted to host nucleic acid sequences from beta-actin and GAPDH. Additionally it has to be mentioned that claims 10 and 11 also relate to non-coding sequences from beta-actin and GAPDH which seems to be inconsistent since both beta-actin and GAPDH are genes which are coding sequences

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.